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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,480	10/23/2003	Silviu Itescu	0575/66602-B/JPW/BJA	2572
7590		08/08/2007		
John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER BUNNER, BRIDGET E	
			ART UNIT	PAPER NUMBER
			1647	
			MAIL DATE	DELIVERY MODE
			08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/693,480

Applicant(s)

ITESCU, SILVIU

Examiner

Bridget E. Bunner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 14, 16, 19, 20, 24, 35-37, 43-52 is/are pending in the application.
- 4a) Of the above claim(s) 1, 10, 14, 16, 19, 20, 24, 44, and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37, 43, 45-49, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 10, 14, 16, 19, 20, 24, 35-37 and 43-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/2/04;10/28/04;12/13/04;1/20/06; 1/3/07.

DETAILED ACTION***Status of Application, Amendments and/or Claims***

The amendments of 23 October 2003, 23 February 2004, 31 July 2006, and 01 June 2007 have been entered in full. Claims 2-9, 11-13, 15, 17, 18, 21-23, 25-34, 38-42 are cancelled. Claims 51-52 are added.

Claims 1, 10, 14, 16, 19, 20, 24, 35-37, and 43-52 are pending.

Election/Restrictions

Applicant's election with traverse of Group V, drawn to claims 35-37, and the species of "intramyocardially" in the reply filed on 08 January 2007 is acknowledged. The traversal is on the ground(s) that the claims of Groups I-V are not independent. Applicant argues that the claims of Groups I-V are related in that they are drawn to similar compounds, compositions, and methods of use. Applicant states that all of the methods relate to treating or preventing a disorder of a tissue involving loss of cells. Applicant also asserts that there would not be a serious burden on the Examiner if restriction were not required and that a search of prior art with regard to any of Groups I-V would identify art for the other Groups. This is not found persuasive because as discussed in detail at pages 4-5 of the Restriction Election of 18 October 2006, the distinct products and processes require separate, distinct, and non-coextensive searches. Groups III and I are related as product and process of use. However, the claimed product can be used in materially different methods. Inventions I, II, IV, and V are related processes. However, each method has different designs and effects since each Group uses a unique combination of compounds or targets a unique molecule. Additionally, searching the inventions of Groups I-V together would impose a serious search burden. The inventions require

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a different field of search (see MPEP § 808.02), as well as a separate status in the art in view of their different classification requirements. The technical literature searches for the inventions of Groups I-V are separate, distinct, and non-coextensive and thus, it would be burdensome to search the inventions of Groups I-V together.

Regarding the second Restriction Election of 27 March 2007, Applicant's election with traverse of Group II, drawn to a method of administering SDF-1 β (claims 35-37, 43-45, 47, 49, 50), the species of "intramyocardially via a stent", and the species of "myocardial infarction" in the reply filed on 01 June 2007 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the Examiner if restriction is not required. Applicant points out that the search would be performed in the same class (514) and subclass (1). Applicant states that searching for stromal-derived factor-1 would presumably return art for each of the three groups. After consideration of the state of the art, Applicant's arguments are found to be persuasive regarding the different inventions. The restriction requirement between Groups I-III from 27 March 2007 is withdrawn and claims 35-37 and 43-50 are hereby rejoined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 10, 14, 16, 19-20, 24, 44, 46, 48, and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on 08 January 2007 and 01 June 2007.

Claims 35-37, 43, 45-49, and 51-52 are under consideration as they read upon the elected species of myocardial infarction and intramyocardial administration via a stent.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 26(a) and Figure 26(b) (see page 15, lines 33-25; page 16, lines 1-3). Deletion of the reference character(s) from the description or corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:

2a. The Brief Description of the Drawings for Figures 30, 31, and 32 do not match the Figures. For instance, the Brief Description for Figure 32 seems to be describing the Figure labeled "Figure 30". The Brief Description for Figure 31 seems to describing the Figure labeled "Figure 32". Finally, the Brief Description for Figure 30 seems to be describing the Figure labeled "Figure 31".

Appropriate correction is required.

Claim Objections

3. Claim 35 is objected to because of the following informalities:

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3a. Claim 35 uses the acronym “CXCR4” without first defining what it represents in the independent claims. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 35-36 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-79, 83, and 85 of copending Application No. 10/512,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating a disorder of tissues involving loss or apoptosis of tissue cells comprising administering an agent effective to cause tissue cell proliferation within the tissue or to inhibit apoptosis of the cells within the tissue. Claim 35 of the instant application recites that the agent

induces activation of CXCR4 (which causes proliferation of the cells or inhibits apoptosis of the cells of the tissue). Claim 36 of the instant application and claim 83 of the '518 application recite that the tissue is heart (cardiac) tissue. Claim 45 of the instant application and claim 79 of the '518 application both recite that the agent is stromal-derived factor-1. Thus, the instant claims are not patentably distinct over the co-pending claims in Application No. 10/512,518.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 35-37, 43, 45-49, and 51-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 69, 77-78, 82-84 of copending Application No. 11/234,879. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating a disorder comprising administering stromal-derived factor-1. Claim 35 of the instant application broadly recites treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue comprising administering an agent which induces activation of CXCR4. Claim 69 of the '879 application recites a method of increasing trafficking of endothelial progenitor cells to an ischemia-damaged tissue in a subject comprising administering stromal-derived factor-1 (which activates CXCR4). Claims 45-49 and 52 of the instant application recite that the agent administered is stromal-derived factor-1 (SDF-1) and specifically, stromal-derived factor-1 α , stromal-derived factor-1 β , and stromal-derived factor-1 γ . As indicated above, claim 69 of the '879 application recites administration of stromal-derived factor-1, and claims 77-78 further recite that the SDF-1 is SDF-1 α and SDF-1 β . Both sets of

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claims also recite that the tissue is heart tissue and that the SDF-1 is administered into the heart.

Both sets of claims also recite that the disorder or subject who is suffering has a myocardial infarction. Thus, the instant claims are not patentably distinct over the co-pending claims in Application No. 11/234,879.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 35-37, 43, 49, and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 35 is directed to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue which comprises administering to the subject an amount of an agent which induces activation of CXCR4 effective to cause proliferation of the cells or inhibit apoptosis of the cells of the tissue within the subject so as to thereby treat the subject. The claims do not require that the agent that activates CXCR4 possess any other

particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of agents.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is not even identification of any particular portion of the agent's structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus of agents that activate CXCR4. Additionally, the description of one agent that activates CXCR4, namely stromal-derived factor-1 (SDF-1), is not adequate written description of an entire genus of agents that induce activation of CXCR4.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the detailed chemical structure of the encompassed agents, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written

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description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only methods using SDF-1 as the agent that activates CXCR4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

7. Claims 35-37, 43, 45-49, and 51-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a subject suffering from myocardial infarction comprising administering human stromal-derived factor-1 α or human stromal-derived factor-1 β , does not reasonably provide enablement for a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue which comprises administering to the subject an amount of an agent which induces activation of CXCR4 effective to cause proliferation of the cells or inhibit apoptosis of the cells of the tissue within the subject so as to thereby treat the subject. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 35 is directed to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue which comprises administering to the subject an amount of an agent which induces activation of CXCR4 effective to cause proliferation of the cells or inhibit apoptosis of the cells of the tissue within the subject so as to thereby treat the subject. Claim 36 recites that the tissue is heart tissue and the cells are cardiomyocytes. Claim 37 recites that the agent is administered intramyocardially via a stent. Claim 45 recites that the agent comprises a human stromal-derived factor-1 (SDF-1). Claims 46-48 recite that the SDF-1 is human SDF-1 α , SDF-1 β , and SDF-1 γ . Claim 49 recites that the disorder is myocardial infarction.

The specification of the instant application teaches that intramyocardial injection of human SDF-1 in rats at 5 peri-infarct sites two days post-LAD ligation results by two weeks in a 5-fold increase in neovascularization and a 44% reduction in apoptotic cardiomyocytes at the per-infarct region relative to control animals receiving intramyocardial saline injections (page 77, lines 8; Figure 19). The specification also discloses that intramyocardial injection of SDF-1 results in a 4.5 fold increase in the number of cycling cardiomyocytes at the peri-infarct region relative to saline-injected animals (page 77, lines 21-28; Figure 20). However, the specification does not disclose the administration of any agent that activates CXCR4, other than SDF-1 α and SDF-1 β , to treat a disorder involving tissue loss or apoptosis. A large quantity of experimentation would be required of the skilled artisan to identify and screen for other agents that bind and activate CXCR4. Such experimentation is considered undue. Tachibana et al.

(Nature 393 : 591-594, 1998) even state that “most chemokine receptors bind more than one ligand, so there may be additional ligands for CXCR4” (page 591, 1st paragraph).

It is also noted that the instant specification (page 21, lines 20-23) and claims 48 and 52 recite that one of the SDF-1 molecules to be administered is human SDF-1 γ . However, at the time the instant invention was made, human SDF-1 γ had not yet been discovered or characterized (see Yu et al. Gene 374: 174-179, 2006). Thus, the specification provides no guidance to one skilled in the art as to how to obtain human SDF-1 γ or that it has the functional activity required by the instant claims.

Furthermore, there is little guidance provided in the instant specification indicating that any agent that activates CXCR4 (including SDF-1), can treat all possible disorders of a tissue involving loss or apoptosis of cells of the tissue. As discussed above, the specification only discloses that administration of SDF-1 to rats with myocardial infarct results in an increase in neovascularization, a reduction in apoptotic cardiomyocytes, and an increase in cycling cardiomyocytes. However, this is not adequate guidance, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The specification teaches that “ ‘[t]issue’ includes heart tissue and, in that embodiment, ‘cells’ include cardiomyocytes. ‘Tissue’ may also include lung, brain, gastrointestinal, liver, kidney and other tissues. ‘Cells’ also includes stem cells which can differentiate into the cell type being lost or progenitors of the cell type being lost in the disorder of the tissue” (page 21, lines 1-6). Thus, undue experimentation would be required of the skilled artisan to treat the numerous tissue disorders that involve loss or apoptosis of the tissue encompassed by the instant claims by administering all possible agents that activate CXCR4. The various disorders encompassed by

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the instant claims have different pathophysiologies and may be recalcitrant to treatment. Thus, the skilled artisan would not be able to predict that all agents that activate CXCR4 (including SDF-1) would be able to treat all possible tissue disorders that involve loss or apoptosis of the tissue. For example, apoptosis and tissue loss is involved in Duchenne muscular dystrophy, metabolic myopathies, spinal muscular atrophy, polycystic kidney diseases, liver disease, and Alzheimer's disease, among others (Tews, DS. Neuromuscl Dis 12: 613-622, 2002; page 616, col 1, 1st full paragraph; page 617, col 1, first full paragraph and col 2, last paragraph;; Woo, D. New Engl J Med 333: 1825, 1995;; Canbay et al., Turk J Gastroenterol 16(1): 1-6, 2005;; Behl, C. J Neural Transm 107: 1325-1344, 2000).

Due to the large quantity of experimentation necessary to identify and screen for agents that activate CXCR4 (such as human SDF-1 γ) and to treat all possible tissue disorders that involve loss or apoptosis of cells of the tissue by administration of such agents; the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to the same; the complex nature of the invention; and the unpredictability of identifying agents that activate CXCR4 and of treating all possible tissue disorders that involve loss or apoptosis of cells of the tissue, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 35-36, 45-46, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Peterson, BE (US 2002/0094327).

Peterson teaches that modulating the level of SDF-1 α protein in a target tissue can selectively direct migration of pluripotent stem cells to the target tissue (page 1, [0006]). Peterson continues to disclose that “[b]y increasing the number of pluripotent stem cells that traffic to the target tissue, the rate of tissue repair can be increased because there will be a greater number of pluripotent stem cells in the target tissue that can differentiate into cells which can repopulate and partially or wholly restore the normal function of the damaged tissue” (page 1, [0006]). Peterson teach a method of targeting a pluripotent stem cell to a target tissue comprising introducing the SDF-1 α protein into the mammalian subject in order to increase the concentration of SDF-1 α in the target tissue (page 1, [0007]). Peterson teaches that target tissues can be any within a mammalian subject, such as heart (page 8, column 2, [0063]). Peterson also discloses that target cells for use in the invention can include any cell in or that migrates to a target tissue (page 8, column 2, [0063]).

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Askari et al. Lancet 362 : 697-703, 2003 (cardiac fibroblasts stably transfected to express SDF-1 are transplanted into injured myocardium)

Peled et al. Blood 95(11) : 3289-3296, 2000 (activation of CD34+ cells with SDF-1 leads to adhesion and transendothelial migration)

Moore et al. Ann NY Acad Sci 938: 36-47, 2001 (intravenous injection of a replication - incompetent adenovector expressing the SDF-1 results in leukocytosis and an increase in platelets)

Nagasawa, T. Ann NY Acad Sci 947: 112-116, 2001 (review of SDF-1 and its role in vascularization)

Rempel et al. Clin Can Res 6 :102-111, 2000 (SDF-1 and CXCR4 proteins are expressed in glioblastoma regions of angiogenesis and degenerative, necrotic, and microcystic changes)

Yamaguchi et al. Circulation 107 : 1322-1328, 2003 (local injection of SDF-1 into athymic ischemic hindlimb muscle of nude mice in conjunction with human endothelial progenitor cell transplantation results in augmented vasculogenesis)

Petit et al. Trends in Immunol 28(7) : 299-307, 2007 (SDF-1-CXCR4 signaling pathway)

Salcedo et al. Am J Pathol 154(4) : 1125-1135, 1999 (subcutaneous injections of SDF-1 α into mice induce formation of local small blood vessels; SDF-1 α acts as a potent chemoattractant for endothelial cells and participates in angiogenesis)

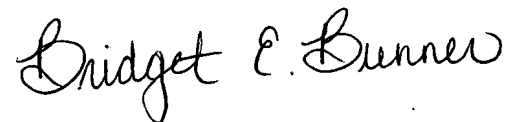
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
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25 July 2007

A handwritten signature in cursive script that reads "Bridget E. Bunner".

**BRIDGET E. BUNNER
PRIMARY EXAMINER**